

(4) “Excessively Radioactive” if the bottled water fails to meet the requirements of paragraph (b)(5) of this section.

(d) *Adulteration*. Bottled water containing a substance at a level considered injurious to health under section 402(a)(1) of the Federal Food, Drug, and Cosmetic Act (the act), or that consists in whole or in part of any filthy, putrid, or decomposed substance, or that is otherwise unfit for food under section 402(a)(3) of the act is deemed to be adulterated, regardless of whether or not the water bears a label statement of substandard quality prescribed by paragraph (c) of this section. If *E. coli* is present in bottled water, then the bottled water will be deemed adulterated under section 402(a)(3) of the act.

[60 FR 57124, Nov. 13, 1995; 60 FR 66495, Dec. 22, 1995, as amended at 61 FR 13264, Mar. 26, 1996; 61 FR 14480, Apr. 2, 1996; 63 FR 25769, May 11, 1998; 66 FR 16865, Mar. 28, 2001; 66 FR 17359, Mar. 30, 2001; 66 FR 35373, July 5, 2001; 66 FR 56035, Nov. 6, 2001; 58 FR 15355, Mar. 31, 2003; 68 FR 9881, Mar. 3, 2003; 70 FR 33700, June 9, 2005; 74 FR 25665, May 29, 2009]

EFFECTIVE DATE NOTE: At 76 FR 64813, Oct. 19, 2011, §165.110 was amended in the table in paragraph (b)(4)(iii)(C), by adding an entry for “Di(2-ethylhexyl)phthalate (117–81–7)”, revising paragraph (b)(4)(iii)(F) introductory text and adding paragraphs (b)(4)(iii)(F)(21) and (b)(4)(iii)(F)(22), effective April 16, 2012. For the convenience of the user, the added and revised text is set forth as follows:

§ 165.110 Bottled water.

* * * *

(b) * * *

(4) * * *

(iii) * * *

(C) The allowable levels for pesticides and other synthetic organic chemicals (SOCs) are as follows:

Contaminant (CAS Reg. No.)	Concentration in milligrams per liter
Di(2-ethylhexyl)phthalate (117–81–7)	0.006

* * * *

(F) Analyses to determine compliance with the requirements of paragraphs (b)(4)(iii)(B) and (b)(4)(iii)(C) of this section shall be con-

ducted in accordance with an applicable method or applicable revisions to the methods listed in paragraphs (b)(4)(iii)(F)(1) through (b)(4)(iii)(F)(22) of this section and described, unless otherwise noted, in “Methods for the Determination of Organic Compounds in Drinking Water,” Office of Research and Development, EMSL, EPA/600/4–88/039, December 1988, or in “Methods for the Determination of Organic Compounds in Drinking Water, Supplement 1,” Office of Research and Development, EMSL, EPA/600/4–90/020, July 1990, or in “Methods for the Determination of Organic Compounds in Drinking Water, Supplement III,” EPA National Exposure Research Laboratory, Office of Research and Development, EPA/600/R–95/131, August 1995, including Errata, November 27, 1995. The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies of these publications are available from National Technical Information Service, U.S. Department of Commerce, 5285 Port Royal Rd., Springfield, VA 22161. You may inspect a copy at the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, 301–827–6860 or at the National Archives and Records Administration (NARA). Hearing-impaired or speech-impaired individuals may access this number through TTY by calling the toll-free Federal Relay Service at 800–877–8339. For information on the availability of this material at NARA, call 202–741–6030, or go to: <http://www.archives.gov/federal-register/cfr/ibr-locations.html>.

(21) Method 506, Rev. 1.1—“Determination of phthalate and adipate esters in drinking water by liquid/liquid extraction or liquid/solid extraction and gas chromatography with photoionization detection,” EPA/600/R–95/131, 1995, (applicable to di(2-ethylhexyl)phthalate), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or

(22) Method 525.2, Rev. 2.0—“Determination of organic compounds in drinking water by liquid-solid extraction and capillary column gas chromatography/mass spectrometry,” EPA/600/R–95/131, 1995, (applicable to di(2-ethylhexyl)phthalate), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51.

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PART 166—MARGARINE

Subpart A—General Provisions

Sec.
166.40 Labeling of margarine.

**Subpart B—Requirements for Specific
Standardized Margarine**

166.110 Margarine.

AUTHORITY: 21 U.S.C. 321, 341, 343, 347, 348, 371, 379e.

Subpart A—General Provisions

§ 166.40 Labeling of margarine.

The Federal Food, Drug, and Cosmetic Act was amended by Pub. L. 459, 81st Congress (64 Stat. 20) on colored oleomargarine or margarine by adding thereto a new section numbered 407. Among other things, this section requires that there appear on the label of the package the word “oleomargarine” or “margarine” in type or lettering at least as large as any other type or lettering on the label, and a full and accurate statement of all the ingredients contained in such oleomargarine or margarine. It provides that these requirements “shall be in addition to and not in lieu of any of the other requirements of this Act”.

(a) Under section 403(g) of the Federal Food, Drug, and Cosmetic Act, any article that is represented as or purports to be oleomargarine or margarine must conform to the definition and standard of identity for oleomargarine or margarine promulgated under section 401 of the act (Subpart B of this part), and its label must bear the name “oleomargarine” or “margarine”.

(b) The identity standard for oleomargarine or margarine applies to both the uncolored and the colored article.

(c) In considering the requirement that the word “oleomargarine” or “margarine” be in type or lettering at least as large as any other type or lettering on the label, it must be borne in mind that at least three factors are involved—the height of each letter, the area occupied by each letter as measured by a closely fitting rectangle drawn around it, and the boldness of letters or breadth of the lines forming the letters. The type or lettering used should meet the following tests:

(1) The height of each letter in the word “oleomargarine” or “margarine” should equal or exceed the height of any other letter elsewhere on the label.

(2) The area of the closely fitting rectangle with respect to any of the let-

ters in the word “oleomargarine” or “margarine” should equal or exceed the area of such rectangle applied to the same or a corresponding letter elsewhere on the label.

(3) The letters in the word “oleomargarine” or “margarine” should be equal to or exceed in prominence and boldness, such as breadth of lines forming the letters, the same or corresponding letters elsewhere on the label.

(d) [Reserved]

(e) The word “oleomargarine” or “margarine” (and thus the other information called for by the statute) should appear on each panel of the package label that might reasonably be selected by the grocer for display purposes at the point of sale.

(f) The amendment covering colored oleomargarine or colored margarine states that, “for the purposes of * * * section 407 of the Federal Food, Drug, and Cosmetic Act, as amended, the term ‘oleomargarine’ or ‘margarine’ includes: (1) All substances, mixtures, and compounds known as oleomargarine or margarine; (2) all substances, mixtures, and compounds which have a consistency similar to that of butter and which contain any edible oils or fats other than milk fat if made in imitation or semblance of butter”. Notwithstanding the difference between this definition and the definition and standard of identity for oleomargarine or margarine promulgated under section 401 of the act, it was the clear intent of Congress that any article which is represented as or purports to be oleomargarine or margarine is misbranded if it fails to comply with the definition and standard of identity for oleomargarine or margarine even though it may meet the statutory definition.

(g) Section 407(a) states that “Colored oleomargarine or colored margarine which is sold in the same State or Territory in which it is produced shall be subject in the same manner and to the same extent to the provisions of this act as if it had been introduced in interstate commerce”.

(h) Section 407(b)(4) requires that each part of the contents of the package be “contained in a wrapper which bears the word ‘oleomargarine’ or

‘margarine’ in type or lettering not smaller than 20-point type”. The Food and Drug Administration interprets this to mean that the height of the actual letters is no less than 20 points, or 20/72 of 1 inch.

(i) The wrappers on the subdivisions of oleomargarine or margarine contained within the package sold at retail are labels within the meaning of section 201(k) and shall contain all of the label information required by sections 403 and 407 of the Federal Food, Drug, and Cosmetic Act, just as in the case of 1-pound cartons, except that wrappers on the subdivisions contained within the retail package shall be exempt from compliance with the requirements of section 403 (e)(1), (g)(2), (i)(2), and (k) of the act with respect to the requirements for label declaration of the name and place of business of the manufacturer, packer, or distributor and label declaration of ingredients when (1) the subdivisions are securely enclosed within and are not intended to be separated from the retail package under conditions of retail sale; (2) the wrappers on the subdivisions are labeled with the statement “This Unit Not Labeled For Retail Sale” in type size not less than one-sixteenth inch in height. The word “Individual” may be used in lieu of or immediately preceding the word “Retail” in the statement.

[42 FR 14477, Mar. 15, 1977, as amended at 46 FR 31005, June 12, 1981; 47 FR 32421, July 27, 1982]

Subpart B—Requirements for Specific Standardized Margarine

§ 166.110 Margarine.

(a) *Description.* Margarine (or oleomargarine) is the food in plastic form or liquid emulsion, containing not less than 80 percent fat determined by the method prescribed in “Official Methods of Analysis of the Association of Official Analytical Chemists,” 13th Ed. (1980), section 16.206, “Indirect Method,” under the heading “Fat (47)—Official Final Action,” which is incorporated by reference. Copies may be obtained from the AOAC INTERNATIONAL, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877, or may be examined at the National Ar-

chives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html. Margarine contains only safe and suitable ingredients, as defined in § 130.3(d) of this chapter. It is produced from one or more of the optional ingredients in paragraph (a)(1) of this section, and one or more of the optional ingredients in paragraph (a)(2) of this section, to which may be added one or more of the optional ingredients in paragraph (b) of this section. Margarine contains vitamin A as provided for in paragraph (a)(3) of this section.

(1) Edible fats and/or oils, or mixtures of these, whose origin is vegetable or rendered animal carcass fats, or any form of oil from a marine species that has been affirmed as GRAS or listed as a food additive for this use, any or all of which may have been subjected to an accepted process of physico-chemical modification. They may contain small amounts of other lipids, such as phosphatides or unsaponifiable constituents, and of free fatty acids naturally present in the fat or oil.

(2) One or more of the following aqueous phase ingredients:

(i) Water and/or milk and/or milk products.

(ii) Suitable edible protein including, but not limited to, the liquid, condensed, or dry form of whey, whey modified by the reduction of lactose and/or minerals, nonlactose containing whey components, albumin, casein, caseinate, vegetable proteins, or soy protein isolate, in amounts not greater than reasonably required to accomplish the desired effect.

(iii) Any mixture of two or more of the articles named under paragraphs (a)(2) (i) and (ii) of this section.

(iv) The ingredients in paragraphs (a)(2) (i), (ii), and (iii) of this section shall be pasteurized and then may be subjected to the action of harmless bacterial starters. One or more of the articles designated in paragraphs (a)(2) (i), (ii), and (iii) of this section is intimately mixed with the edible fat and/or ingredients to form a solidified or liquid emulsion.

(3) Vitamin A in such quantity that the finished margarine contains not less than 15,000 international units per pound.

(b) *Optional ingredients.* (1) Vitamin D in such quantity that the finished oleo-margarine contains not less than 1,500 international units of vitamin D per pound.

(2) Salt (sodium chloride); potassium chloride for dietary margarine or oleo-margarine.

(3) Nutritive carbohydrate sweeteners.

(4) Emulsifiers.

(5) Preservatives including but not limited to the following within these maximum amounts in percent by weight of the finished food: Sorbic acid, benzoic acid and their sodium, potassium, and calcium salts, individually, 0.1 percent, or in combination, 0.2 percent, expressed as the acids; calcium disodium EDTA, 0.0075 percent; propyl, octyl, and dodecyl gallates, BHT, BHA, ascorbyl palmitate, ascorbyl stearate, all individually or in combination, 0.02 percent; stearyl citrate, 0.15 percent; isopropyl citrate mixture, 0.02 percent.

(6) Color additives. For the purpose of this subparagraph, provitamin A (beta-carotene) shall be deemed to be a color additive.

(7) Flavoring substances. If the flavoring ingredients impart to the food a flavor other than in semblance of butter, the characterizing flavor shall be declared as part of the name of the food in accordance with §101.22 of this chapter.

(8) Acidulants.

(9) Alkalizers.

(c) *Nomenclature.* The name of the food for which a definition and standard of identity are prescribed in this section is “margarine” or “oleo-margarine”.

(d) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter. For the purposes of this section the use of the term “milk” unqualified means milk from cows. If any milk other than cow’s milk is used in whole or in part, the animal source shall be identified in conjunction with the word milk in the ingredient state-

ment. Colored margarine shall be subject to the provisions of section 407 of the Federal Food, Drug, and Cosmetic Act as amended.

[42 FR 14478, Mar. 15, 1977, as amended at 47 FR 11834, Mar. 19, 1982; 48 FR 13024, Mar. 29, 1983; 49 FR 10103, Mar. 19, 1984; 54 FR 24896, June 12, 1989; 58 FR 2886, Jan. 6, 1993; 58 FR 21649, Apr. 23, 1993; 59 FR 26939, May 25, 1994; 63 FR 14035, Mar. 24, 1998]

PART 168—SWEETENERS AND TABLE SIRUPS

Subpart A [Reserved]

Subpart B—Requirements for Specific Standardized Sweeteners and Table Sirups

Sec.

168.110 Dextrose anhydrous.

168.111 Dextrose monohydrate.

168.120 Glucose sirup.

168.121 Dried glucose sirup.

168.122 Lactose.

168.130 Cane sirup.

168.140 Maple sirup.

168.160 Sorghum sirup.

168.180 Table sirup.

AUTHORITY: 21 U.S.C. 321, 341, 343, 348, 371, 379e.

SOURCE: 42 FR 14479, Mar. 15, 1977, unless otherwise noted.

Subpart A [Reserved]

Subpart B—Requirements for Specific Standardized Sweeteners and Table Sirups

§ 168.110 Dextrose anhydrous.

(a) Dextrose anhydrous is purified and crystallized D-glucose without water of crystallization and conforms to the specifications of §168.111, except that the total solids content is not less than 98.0 percent m/m.

(b) The name of the food is “Dextrose anhydrous” or “Anhydrous dextrose” or alternatively, “_____ sugar anhydrous” or “Anhydrous sugar”, with the blank to be filled with the name of the food source, for example, “Corn sugar anhydrous”.

[42 FR 14479, Mar. 15, 1977, as amended at 58 FR 2886, Jan. 6, 1993]